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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,218	08/16/2000	Miroslav Colic	4904-4	3341

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 09/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/640,218

Applicant(s)

COLIC, MIROSLAV

Examiner

Joseph Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3-8 and 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,9 and 10 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

This application filed August 16, 2000, claims benefit to provisional application 60/149,131, filed August 16, 1999.

#### ***Election/Restriction***

Applicant's election of Group I, claims 1, 2, 9 and 10, in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-14 are pending. Claims 3-8 and 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 5. Claims 1, 2, 9 and 10 as directed to a pharmaceutical composition encompassing a silica containing solid containing silica with no additional components, are currently under examination.

#### ***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

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An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

***Claim objections***

Claim 9 is objected to for the following informalities: the claim recites "silica-containing" however this appears to be a typographical error because this is not a hyphenated word.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 1, 2, 9 and 10 are unclear and confusing in the recitation of "silica containing solid" because silica is a solid insoluble particle (specification page 10). It is unclear if the silica is being referred to as a solid, and thus, does not encompass gels or colloids of silica, or if the silica contains a composition which is solid. Further, claim 1 is unclear in the recitation of "having an average particle size of about 6 microns" because it is not clear if this in reference to a silica particle or if it is in reference to a solid contained within the silica particle.

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Claim 9 is unclear and confusing because it appears to be a method step of removing the aluminum from a silica, however claim 1 is a product, not a method. Further, silica does not inherently comprise aluminum, and it is unclear if a composition comprising silica and not containing aluminum would inherently meet the limitations of this claim.

In claim 10, the recitation of "the pores" lacks explicit antecedent basis in claim 1. It is unclear if the silica or the solid contains the pores, or if each/both of these would inherently contain pores. Further, silica in a crystal form do not have pores.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorn *et al.* (US Patent 4,927,750).

Claim 1 is drawn to a composition comprising silica having an average size of 6 microns or less, and dependent claims 2 define possible types of silicas and claim 10 describes further modifications of the composition. Dependent claim 9 is a silica composition which does not contain aluminum. Dorn *et al.* describe a composition comprising silica with the preferred particle size of about 30-220 angstroms (column 2; lines 15-17) and as large as 600 angstroms

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(column 6; line 66). It is taught that the silica compositions can be further modified by coating the particles with a variety of polymers each which would uniquely affect the property of the silica particle (column 2; lines 26-42). Dorn *et al.* teach that some silicas themselves are toxic to certain cell types and attempts have been made to reduce the toxicity (column 2, lines 23-26). In one case aluminum was chemically incorporated into the silica to produce the commercially available colloidal silica Ludox AM<sup>R</sup> (column 2; lines 57-68). By extension Ludox AM<sup>R</sup> as well as other silicas which are taught in which aluminum was not specifically added would not contain aluminum. Additionally, the compositions taught by Dorn *et al.* can be designed to be non-toxic to cells and used to isolate living cells, and therefore, could be used in other forms of pharmaceutical compositions. Because each of the limitations set forth in the claims is taught by Dorn *et al.*, the compositions comprising silica taught by Dorn *et al.* anticipate the claims.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bollon *et al.* (US Patent 4,029,631) as evidenced by Dorn (US Patent 4,927,750).

Claim 1 is drawn to a composition comprising silica having an average size of 6 microns or less. Dependent claims 2 define possible types of silicas.

Bollon *et al.* describe a composition comprising silica with the preferred particle size of about 2-6 microns (claim 6 and column 3; lines 31-32) which can be used with pharmaceuticals (column 3; line 61). Preferred embodiments teach that the compositions disclosed by Bollon *et al.* are prepared from the specific silica silicon tetrachloride (column 4; lines 19-21 and claim 5).

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As noted above, Dorn *et al.* teach that silicas themselves are toxic to certain cell types and thus can serve as pharmaceutical compositions (column 2, lines 23-26). However, it is also noted that the office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989).

Bollon *et al.* teach silica containing compositions meeting the limitations set forth in the claims, therefore Bollon *et al.* anticipates the claims.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Voitach

  
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